

K970564

**510 (k) SUMMARY**

**MITSUBISHI LINEAR ACCELERATORS  
EXL SERIES**

MAY 12 1997

**1. Submitter:**

The 510 (k) is submitted by Mr. Hideyuki Kawakami, Sales Manager, Medical Systems Division, Mitsubishi Electronics America, Inc., Two Tower Bridge, 1 Fayette Street, Suite 100, Conshohocken, PA 19428. This 510 (k) summary was prepared on February 6, 1997.

**2. Device Name:**

The 510 (k) submission is for Mitsubishi Dynamic Wedge system, an additional function to Mitsubishi multileaf collimator (MLC) as well as the conventional monoblock collimator.

The predicate device is legally marketed, having been found to be substantially equivalent through the 510 (k) premarket notification process.

**3. Predicate device:**

The devices described in this submission are considered to be substantially equivalent to the EXL series of Mitsubishi Linear Accelerators utilizing klystron and magnetron power supplies and conventional hard-wired control consoles. The predicate device are legally marketed, having been found to be substantially equivalent through the 510 (k) premarket notification process.

**4. Device description:**

This submission is intended to be applicable to the Dynamic Wedge system which can be used with multileaf collimator system on Mitsubishi linear accelerators for external beam radiotherapy. The Dynamic Wedge system is designed to create effective isodose curve by using collimator leaf drive during irradiation. The Dynamic Wedge system consists of the collimator, motor drive unit (MDU), local control equipment (LCE) located in the treatment room, control console, and data management equipment (DME).

The collimator consists of two sets of jaws which determines the field size and shape. The upper jaws consist of a pair of monoblocks just like conventional accelerator therapy collimators. The upper jaws move in tandem and determine the field length.

The lower set of jaws consist of 31 pairs of leaves (62 leaves).

Each pair of leaves is independently driven by a stepping motor. Each pair of leaves can be independently set to provide irregular-shaped field settings.

**5. Intended use:**

The Dynamic Wedge system is intended to be used with MLC and Mitsubishi linear accelerators with computerized consoles to provide the effective isodose curve and replace the need for traditional hard wedges.

**6. Comparison of technological characteristics:**

This submission describes the modification of existing Mitsubishi MLC system by adding data management equipment (DME) to transfer treatment data for Dynamic Wedge.

Monoblock type collimator can also be used by simply deleting functions to control lower leaves for MLC system.